David R. Gifford, MD, MPH
Director of Health

Three Capitol Hill
Providence, RI 02908-5097

401.222.2231
401.222.6548 Fax
TTY: 711
www.health.ri.gov

October 26, 2010

Timothy J. Babineau, MD, CEO
Rhode Island Hospital
593 Eddy Street
Providence, Rhode Island 02902

Dear Dr. Babineau,

The Department of Health concluded our joint investigation with the Center for Medicare & Medicaid Services (CMS) at Rhode Island Hospital (RIH) regarding the retained foreign object (RFO) after surgery (the broken drill bit from the August 4th neurosurgery). The Department's findings and Statement of Deficiencies (SOD) are enclosed. CMS will be issuing their findings and sanctions in a separate form. Pursuant to the provisions of the "Rules and Regulations for Licensing of Hospitals," the Hospital is required to file a Plan of Corrections with the Department of Health within fifteen (15) calendar days.

While the hospital policy for surgical counts appears to be appropriate and the rate of RFOs after surgery does not appear to be greater than the national average, the significant problem we identified, once again, is the failure of RIH staff to follow hospital policy. During this most recent "never event", the staff and surgeon were aware in the operating room that the drill bit had broken. They could not locate the broken piece. The surgeon stated that he thought it might be in the surgical flap. The operating room nurse asked for guidance from her manager who reportedly told her to put the drill bit pieces in a bag. No discussion occurred about obtaining an X-ray to ensure the drill bit was not in the patient despite the fact that your hospital policy (which is consistent with the national standard of care) clearly articulates that an X-ray should be obtained prior to the patient leaving the operating room with a suspected RFO. In addition, the surgical count was recorded as normal. These actions resulted in the patient being placed at significant risk of harm when she had a "routine" MRI the next day while having a metallic piece of a drill bit in her surgical wound. The continued failure of the hospital to ensure that operating room staff (including physicians) follow existing policies remains very troubling.

Of even greater concern is the failure of the hospital to adequately address numerous reports by staff of problems they identified that could result it medical errors. For example, staff reported that the surgical count process for sponges and medical equipment was often incorrect, which as you know could lead to an RFO. Yet, we did not find any evidence that appropriate action was taken by hospital management to address this significant problem. This increases the likelihood of a RFO event at Rhode Island Hospital. Similarly, reports by nursing of an anesthesiologist not wearing his surgical mask in the operating room were never addressed by medical leadership.

These findings combined with the findings related to prior wrong site surgeries, reflect a troubling pattern of disregard of policies designed to address patient safety and prevent medical errors. Thus, the Department finds that additional sanction is necessary to alert

the medical staff, hospital leadership and hospital board to the serious nature and urgency of improving patient safety at Rhode Island Hospital.

Therefore, in addition to the enclosed deficiencies, Rhode Island Hospital is issued a third fine in the amount of three hundred thousand dollars ($300,000). The Hospital is herby required to submit payment of this fine within (30) days of the receipt of this letter, made payable to the State of Rhode Island General Treasurer. If the Hospital is aggrieved by the discipline set forth in this letter, the Hospital may request a hearing of these matters within thirty (30) days.

If you have any questions, please contact me either in writing or at 222-2232 or contact Adelita Orefice, Executive Director, Environmental and Health Services Regulation at 222-4727.

Sincerely,

David R. Gifford, MD, MPH
Director, Rhode Island Department of Health

Encl: Statement of Deficiencies

cc:
Lawrence Auburn, Sr., Board Chair Rhode Island Hospital
George A. Vecchione, CEO Lifespan
Alfred J. Verrecchia, Board Chair, Lifespan
Richard M. Shaw, Centers for Medicare and Medicaid Services

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 095	ORGANIZATION & MANAGEMENT 9.1 Quality Improvement Section 9.0 Quality Improvement 9.1 The governing body shall ensure that there is an effective, ongoing, hospital-wide quality improvement program to evaluate the provision of patient care. This Requirement is not met as evidenced by: Based on review of the hospital policies entitled, "Surgical Counts", and "Universal Protocol: Verification of the Patient's Identity, Surgical Procedure and Surgical Site/Side" related to Debriefing, the Medical Event Reporting System, Surgical Executive Committee Meeting Minutes, Surgical Occurrence Reports, medical record review, and staff interviews, it was determined the governing body failed to ensure an effective hospital-wide quality improvement program. Findings are as follows: 1. Evidence of the failure to analyze causes of adverse patient events. (Refer to Z 105) 2. Evidence of the failure to ensure that all surgical services and adverse events are evaluated for appropriateness. (Refer to Z 115). 3. Evidence of the failure to take and document appropriate remedial action to address problems identified. (Refer to Z 120).	Z 095		
Z 105	ORGANIZATION & MANAGEMENT 9.3 Quality Improvement 9.3 All patient care services, including services rendered by a contractor, shall be evaluated. This Requirement is not met as evidenced by: Based on medical record review, review of Surgical Occurrence reports, the MERS (Medical	Z 105		

Facilities Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ___ B. WING ___	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 105	Continued From page 1	Z 105		

Event Reporting System) reports that include areas entitled Event Registration Report and Event Discovery Report, the Operating Room Policy & Procedure related to the "Surgical Counts" protocol, and staff interviews, it was determined that the hospital failed to evaluate adverse patient events for relevant sample patient ID #24, and for 10 other identified patients.

Findings are as follows:

1. A review of the surgical record for patient ID #24 revealed an admission to the hospital on 8/3/10 with a diagnosis of abdominal aneurism without rupture. Surgery was performed on 8/4/10. A review of the hospital discharge summary revealed that the procedure was "tolerated well", and a surgical post-op note dated 8/4/10 at 2200 hours revealed "no complications".

According to the Operating Room Policy & Procedure Manual, Section V, "Surgical Counts" protocol, "the first count is done before closure and the final count is done at skin closure or at the end of the procedure".

A review of the patient's Intraoperative Report revealed that the first count for sharps and instruments was "incorrect", and the final sharps and instrument count remained "incorrect".
A surgical occurrence report was completed on 8/4/10. The Event Description portion of the report reveals that the sharps first and final counts were "incorrect". An instrument count was partially completed, then aborted by the Surgeon.

During an interview with the Director of Quality/Patient Safety Perioperative Services on 10/6/10 at 9:30 AM, she was questioned

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 105	Continued From page 2	Z 105		

regarding the incorrect counts. It was reported that the "surgeon was in a hurry" and had told the operating room team to "stop the count". When asked why, it was reported that "there must have been a lot going on in the suite".

The MERS Event Registration Report identified factors involved with this event that included "inadequate/absent communication; staff related clinical judgment/skill/competence and distraction/interruption/inattention". Although this report also identified that the event "probably" could have been prevented or could be prevented in the future, it failed to provide actions. This report, under Manager's comments, stated, "team should have stopped to complete count". The Event Discovery Report area indicated, "when closing, the Scrub Tech was prompted to begin surgical counts and refused. Although the surgical counts began too late in the procedure, the Circulating Nurse made every attempt to redirect the Scrub Tech to complete the instrument count. X-ray taken...."

Although during an interview with the Director of Quality/Patient Safety Perioperative Services on 10/6/10 at 9:30 AM, she reported that the only actions taken had been to "re-educate staff" and that the Surgeon was "spoken to", she was unable to provide any supporting evidence. It was further stated that the hospital encourages the reporting of "good catches", and the actions taken are usually re-education so good catch reporting is not reduced.

During an interview, on 10/7/10, with the Surgical Director of the Perioperative area, due to the unavailability of the Surgeon in this case, he reported that if the counts were not done, the medical record should indicate why protocol was

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 105	Continued From page 3	Z 105		

not followed. The medical record failed to contain this information..

2. The hospital policy entitled, "Surgical Counts", Section V, Protocols/Standards, under "Procedural Guidelines-General Considerations", states:

"When additional items are added to the field, they should be counted and recorded on the count sheet."

A review of the occurrences for surgical services from 1/1/10 through 10/1/10 included instances where extra sharps/instruments were noted during the counts that were unexplained, with no follow-up to determine causal factors in order to determine priorities for performance improvement.

Occurrence examples include:

9/29/10 "... incorrect needle count and instrument count. More needles on field than on count pad"

8/19/10 " ... three (3) Bovie tips on the field but the documentation indicates only two (2)"

7/22/10 "... one (1) more needle holder on field"

6/8/10 " ... extra retractors found while doing the instrument count"

4/14/10 "... incorrect needle holder count. Count was over by one (1) needle holder"

2/24/10 "... incorrect instrument count. Extra pieces to Thompson Retractor on field, and not accounted for on the count sheet"

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 105	Continued From page 4 2/2/10" ... incorrect instrument count. Towel clips on field not on count sheet" 1/27/10 "... sponge count incorrect. Surgical field had one more sponge than on count pad" 1/26/10 "... incorrect count. Extra instrument on the field" Another example, of a 4/15/10 Occurrence Report revealed "numerous needles put out on the field at various times by different employees." On 10/6/10, the Risk Manager was asked to provide a copy of the hospital's investigation related to this Occurrence Report. In response, an interview on 10/6/10, with the Administrative Director of Perioperative Services was conducted. She confirmed that no investigation was done, and she could not explain the Occurrence Report or why there was no follow up. During an interview on 10/6/10 at 8:25 AM with the both Administrative Director of Perioperative Services and the Director of Quality/Patient Safety Perioperative Services, it was reported that when the count is incorrect and extra instruments/sharps/sponges are found, the Circulating Nurse is responsible to add it to the count. There was no evidence that this occurred for the above occurrences, and no evidence of remedial actions. For all above cases, the hospital failed to analyze the causes for the unreconciled counts.	Z 105		
Z 115	ORGANIZATION & MANAGEMENT 9.5 Quality Improvement	Z 115		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 115	Continued From page 5	Z 115		

9.5 All medical and surgical services performed in the hospital shall be evaluated for appropriateness in diagnosis and treatment. The evaluation shall include peer review of individual cases. The hospital shall maintain records of peer reviews, documenting the case(s) reviewed, focus of each review, findings, conclusions, any actions taken, and any follow-up on actions taken.
This Requirement is not met as evidenced by:
Based on medical record review, the Surgical Executive Committee Meeting minutes, the MERS (Medical Error Reporting System), and staff interview, it was determined that the hospital failed to ensure that all surgical services, including adverse events, are evaluated for appropriateness.

Findings are as follows:

A review of the MERS revealed that on 9/21/10, an Anesthesiologist had "another incident" of entering a sterile Operating Room without being appropriately attired. The Occurrence Report indicated that this Anesthesiologist had "on numerous times" been told to put the (surgical) mask up. On 9/21/10, the Anesthesiologist "made like he held his breath" and walked through the operating room, again being told not to do so. The Anesthesiologist at that time "made a joke about it and continued on".

Although the occurrence report also indicated this should go to his Chief, and the Surgical Executive Committee (SEC), SEC meeting minutes review revealed no evidence that this occurrence was presented to the Surgical Executive Committee.

During an interview with the Chief of Anesthesia on 10/7/10 at 9:05 AM, he reported that "this was

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 115	Continued From page 6 the first time he had heard of the situation", although he did report that action taken regarding the Anesthesiologist included being "pulled aside and spoken to". When asked to provide written evidence of the action taken, the response was that "nothing had been documented". A review of the MERS Event Discovery Report identified concerns in the Anesthesia Department related to infection control and aseptic technique. The Performance Improvement area on the report indicated that as a "result of this event-no additional action taken", and the section for comments by the Manager was blank. During an interview on 10/6/10 at 8:00 with the Administrative Director of the Perioperative area, she indicated that the Manager should have completed the review, she was unable to state how many times the Anesthesiologist may not have followed standards of aseptic technique, and could not explain what "numerous" meant in the report. 2) Refer to Z 105	Z 115		
Z 120	ORGANIZATION & MANAGEMENT 9.6 Quality Improvement 9.6 The hospital shall take and document appropriate remedial action to address problems identified through the quality improvement program. The outcome(s) of the remedial action shall be documented. This Requirement is not met as evidenced by: Based on review of occurrence reports, review of the hospital's Operating Room Policies and Procedures manual, specifically the hospital policy entitled, "Surgical Counts", and staff interview, it was determined that the hospital	Z 120		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 120	Continued From page 7 failed to take and document appropriate remedial action to address problems identified regarding incorrect surgical counts. Findings are as follows: Refer to Z 105	Z 120		
Z 160	ORGANIZATION & MANAGEMENT 12.2 Organization 12.2 Each hospital department and service shall maintain: a) clearly written definitions of its organization, authority, responsibility and relationships; b) written patient care policies and procedures; and c) written provision for systematic evaluation of programs and services. This Requirement is not met as evidenced by: Based on clinical record review, review of hospital policies and procedures, and staff interview, it was determined that the hospital failed to ensure compliance with the following hospital policies: 1) "Surgical Counts" for relevant sample patient (ID #2); 2) Verification Protocol: Verification of the Patient's Identity, Surgical Procedure and Surgical Site/Side" relevant to the Debriefing Process, for 4 of 4 relevant sample patients (ID #'s 20, 21, 22, and 23); and, 3) "Medical Record Documentation Requirements", for 12 of 16 relevant sample patient records (ID#'s 2, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22, 24). Findings are as follows:	Z 160		

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 8	Z 160		

1) The hospital policy entitled, "Surgical Counts", under "Instruments" states:

"Members of the surgical team should account for disassembled or broken instruments in their entirety, including all parts of the instruments."

Under "Incorrect Counts" it states:

"If the count is incorrect and not reconciled after two counts and the item cannot be located, an X-ray will be taken in the OR...."

Additionally, the hospital policy entitled, "Universal Protocol: Verification of the Patient's Identity, Surgical Procedure and Surgical Site/Side", under item #4) "Debriefing Process" states:

"The attending surgeon will initiate a debriefing prior to leaving the Operating Room. All team members are to be actively involved in this process......Identification of any instrument or equipment concerns ....Request by the attending surgeon for any questions, comments from the team."

A review of the medical record for patient ID #2 revealed that a right parietal craniotomy for resection of tumor was performed on 8/4/10. The Operative Report revealed that during the procedure a high-speed air drill was used to make a single burr hole in the inferior portion of the skull that had been exposed. At the conclusion of the case all sponge and needle counts were noted to be correct.

An undated/untimed addendum to the Operative Report revealed that a small fragment of drill bit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 9	Z 160		

was fractured during the opening of the craniotomy. The surgical procedure concluded with no evidence that the drill bit was located.

The patient was admitted postoperatively to the Neurological Intensive Care Unit as planned. A physician progress note, dated 8/4/10, revealed "status post parietal craniotomy, doing well".

On 8/5/10 at 0310, a routine post operative MRI (Magnetic Resonance Technology) was performed. The MRI reading was found to be "non diagnostic secondary to extensive artifact, that obscured the visualization of the resection cavity". An addendum on 8/5/10 at 8:01 PM revealed that "there is a small radiopaque foreign body which represents the artifact and Neurosurgery is aware of the findings".

On 8/5/10 at 0951, a skull Xray (2 views) was performed, and revealed that "two adjacent craniotomy defects are present in the right parietal region". At 8:01 PM, an addendum to this report noted "additional clinical information provided relative to concern that a small fragment of a drill bit cracked in the Operating Room".

On 8/6/10 the patient returned to the Operating Room for removal of a "foreign body". The patient underwent a "right cranial wound exploration for removal of foreign body". The Operative Report revealed a retained foreign body, "approximately 7 mm (millimeters) in length of broken drill bit".

During an interview on 9/30/10 at 10:45 AM with the Vice President of Risk Management, she reported that the Circulating Nurse had contacted the Assistant Clinical Manager for guidance during the initial surgery when the drill bit broke,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 10	Z 160		

and was instructed to collect all pieces in a bag and complete an Occurrence Report. The broken drill bit piece was not obtained.

During an interview on 9/30/10 at 11:00 AM with the Director of Quality/Patient Safety Perioperative Services, it was reported that the Surgeon should have reconciled the broken drill piece either visually or by X-ray when it was not located. An X-ray was not performed prior to the cranial flap placement on the patient when the broken piece of drill bit could not be located, per hospital policy. There was no evidence that the Surgical team identified any equipment concerns during the Debriefing Process at the conclusion of the procedure, per hospital policy. Additionally, the Surgical team also failed to account for the broken piece of equipment during the Surgical Counts at the end of the procedure, in accordance with hospital policy.

During an interview on 9/30/10 at 2:00 PM with 1 of 2 Scrub Technicians, it was determined that she had been precepting the other other Scrub Technician that was recently transferred to the Neurosurgery area. She reported that although she was present for the first count, she was not present for the final count nor the debriefing process. She returned to the operating room when the procedure had concluded and the patient was on a stretcher. She reported that it is the responsibility of the Scrub Tech to ensure that all equipment pieces are in place. The precepting Scrub Tech revealed that she left the orienting Scrub Tech, as he was an experienced Scrub Tech and she assumed he would ask if he had any questions.

During an interview on 9/30/10 at 2:40 PM with the Neurosurgeon, he reported that during the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ___ B. WING ___	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 11 operative procedure on 8/4/10 the drill bit broke and a new drill bit was obtained. He indicated that he "thought that the broken piece may have been in the bone flap that was handed to the Scrub Tech". The Circulating Nurse did question him as to where the broken piece was. The procedure continued, and the scalp was closed by the Neurosurgery Resident. The Neurosurgeon did remain in the room while the sponge and needle counts were completed. He revealed that an X-ray had not been done as he "assumed that the drill bit was found". He admitted that although a debriefing was done, it did not include dialogue relative to the broken piece of equipment. Although the hospital has policies and procedures in place to account for surgical counts and equipment, all parts of these procedures were not implemented. Specifically, the surgical team failed to account for a broken instrument (drill bit) or obtain an Xray at the time that the broken drill bit could not be located; and prior to leaving the OR, the attending surgeon failed to identify instrument or equipment concerns related to the broken drill bit during his debriefing. 2) A review of the hospital policy entitled, "Verification Protocol: Verification of the Patient's Identity, Surgical Procedure and Surgical Site/Side", under item #4 "Debriefing Process" states: "The attending surgeon will initiate a debriefing prior to leaving the operating room. ALL team members are to be actively involved in this process. The surgeon initiates the debriefing by saying, 'Let's begin the debriefing'. The debriefing must include the confirmation of the	Z 160		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ___ B. WING ___	(X3) DATE SURVEY COMPLETED C 10/07/2010
NAME OF PROVIDER OR SUPPLIER: RHODE ISLAND HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE: 593 EDDY STREET PROVIDENCE, RI 02902		

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 12	Z 160		

procedure performed and specimen labeling and destination communicated."

1. Medical Record review for patient ID #20 revealed an admission to the hospital for a surgical procedure in December, 2009. Review of the Perioperative Verification Checklist revealed there is no place on the form for date, time or signature and there is no evidence in the medical record that indicated the surgical debriefing was done according to policy.

The patient was readmitted on 4/7/10 for another surgical procedure. This readmission also failed to contain any evidence that the debriefing was conducted.

2. A review of the medical record for patient ID #21 revealed a hospital admission on 4/27/10. The Perioperative Verification form revealed no evidence that a surgical debriefing was conducted.

3. A review of the medical record for patient ID #22 revealed that the patient was admitted to the hospital on 1/11/10. The Perioperative Verification Form revealed no evidence that the a surgical debriefing was conducted.

4. Review of the medical record for patient ID #23 revealed that the patient was admitted on 9/17/10. The Perioperative Verification form revealed no evidence that a surgical debriefing was conducted.

During an interview 10/7/10 at 8:15 AM with the Administrative Director of Perioperative Services, she was unable to provide evidence that the Debriefing Process was documented anywhere as being conducted.

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HOS00121	A. BUILDING ____ B. WING ____	C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 13	Z 160		

3) A review of the hospital policy entitled, "Medical Record Documentation Requirements", under "Procedure" states:

"Every clinical record entry must be dated, timed, its author identified and authenticated".

1. A review of the medical record for patient ID #2 revealed an admission to the hospital on 8/2/10. A Progress Note dated 8/4/10, and a Neurology note dated 8/5/10 did not include the time of the entry. Additionally, a Pre-op Assessment note and a Surgical Prep Checklist failed to include the time of entry.

2. A review of the medical record for patient ID #12 revealed an admission to the hospital on 8/16/10 . Progress Notes dated 8/17/10, 8/18/10, and 8/23/10, an Anesthesia note dated 8/17/10, and a "Brief Operative Note" dated 8/18/10 did not include a time of entry.

3. A review of the medical record for patient ID #13 revealed an admission to the hospital on 8/17/10. Progress Notes dated 8/17/10, 8/19/10, 8/20/10, 8/21/10, 8/22/10, 8/23/10, 8/24/10, and 8/25/10, a Cardiology note dated 8/18/10, and a Case Management note dated 8/26/10 did not include a time of entry.

4. A review of the medical record for patient ID #14 revealed an admission to the hospital on 8/2/10. Progress Notes dated 8/2/10, 8/3/10, 8/4/10, 8/5/10 and 8/6/10, and a Surgical Procedure Record dated 8/3/10 did not include a time of entry.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 14 5. A review of the medical record for patient ID #15 revealed an admission to the hospital on 9/10/10. Progress Notes dated 9/10/10, 9/13/10, 9/15/10, and 9/25/10, an "OP" note dated 9/15/10, and Clinical Nutrition note dated 9/24/10 did not include a time of entry. 6. A review of the medical record for patient ID #16 revealed an admission to the hospital on 8/17/10. An Operative Note dated 8/17/10, Progress Notes dated 8/18/10, 8/19/10, 8/20/10 and 8/22/10, and a Case Management note dated 8/21/10 did not include a time of entry. 7. A review of the medical record for patient ID #17 revealed an admission to the hospital on 8/25/10. An Operative note dated 8/25/10, Progress Notes dated 8/26/10, 8/28/10, 8/29/10 and 8/30/10, and a Case Management note dated 8/30/10 did not include a time of entry. 8. A review of the medical record for patient ID #18 revealed an admission to the hospital on 8/31/10. The Perioperative Verification Checklist, the Holding Unit Assessment, the Surgical Procedure Record, and the Operative Note, all dated 8/31/10, failed to reveal times of entry. In addition, Progress Notes dated 9/1/10 and 9/2/10, and a Case Management note dated 9/3/10 did not include a time of entry. 9. A review of the medical record for patient ID #20 revealed an admission to the hospital on 12/12/09. Progress Notes dated 12/12/09 and 12/14/09 were not timed. A Perioperative note failed to have the date or time recorded. An Ambulatory PACU (Post Anesthesia Care Unit) order failed to have the date or time recorded A readmission Progress Note dated 1/9/10 was not timed. Additionally a Surgical note dated 4/8/10	Z 160		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	Continued From page 15 had no date, time, or signature of the individual writing the note. 10. A review of the medical record for patient ID #21 revealed an admission to the hospital on 4/27/10. Progress Notes dated 4/28/10 and 4/29/10 did not include the time of the entry. Additionally there was no time on the Colon Rectum Staging Form. 11. A review of the medical record for patient ID #22 revealed an admission to the hospital on 1/11/10. Physician orders on the Surgical Procedure Record did not include the time, and the discharge order to home failed to include the time. The Ambulatory PACU order failed to have time recorded. 12. A review of the medical record for patient ID #24 revealed an admission to the hospital on 8/3/10. An Emergency Room Physician Record had no physician signature, date or time. A Progress note dated 8/3/10, a Cardiology attending note dated 8/4/10 had no time, progress notes dated 8/5/10, 8/6/10 and 8/7/10, and a Vascular Attending note dated 8/8/10 did not include the time of entry. The hospital failed to implement procedures related to documentation of date and/or time of entries in medical records.	Z 160		
Z 370	PATIENT CARE SERVICES 19.6 Patient Care Management 19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by:	Z 370		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HOS00121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 370	Continued From page 16 Based on record review and staff interview it was determined that the hospital failed to provide care and services to all patients in accordance with the prevailing community standard of care related to the provisions of Chapter 5-37 of the RI General Laws, and related to surgical services provided to patient ID #2. Findings are as follows: 1) Chapter 5-37, related to the Board of Medical Licensure and Discipline (BMLD), Section 5-37-9.1, item (3) states: "Reports by any hospital or state or local professional medical association/society of disciplinary action taken against any physician" are to be reported to the BMLD at the RI Department of Health. The hospital failed to report a disciplinary action (a 4 day suspension) taken against a physician, to the BMLD, in August 2010. 2) Refer to Z 160	Z 370		